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Proposed Re-evaluation Decision PRVD2010-11

Tributyltin Compounds

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Proposed Re-evaluation Decision

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for the tributyltin compounds and presents the reasons for the proposed re-evaluation decision.

Tributyltin compounds consisting of tributyltin oxide (BTO) and tri-n-butyltin maleate (TBM) are actives which are under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). In Canada, the use of tributyltin compounds in antifouling paints was prohibited in 2002 (Special Review Decision SRD2002-1). The purpose of the current re-evaluation is to examine the remaining uses for these fungicides as material preservatives in textiles, leather, paper and wood.

Following the re-evaluation announcement for tributyltin oxide, the registrant of the technical grade active ingredient (a.i.) in Canada indicated that they did not intend to support its use as a wood preservative. Further, notice has been submitted of their intent to discontinue sales of tributyltin oxide technical grade products (Biomet TBTO; Registration No. 18077). The use of tri-n-butyltin maleate as a material preservative continues to be supported by the registrant. Appendix I lists all tributyltin products that are registered as of 11 December 2009, under the authority of the *Pest Control Products Act (PCPA)*.

An evaluation of available scientific information found that tributyltin compounds are classified as Track 1 substances under the federal Toxic Substances Management Policy (TSMP). The TSMP is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, i.e., CEPA-toxic or equivalent, predominantly anthropogenic, persistent (in one media) and bioaccumulative).

[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

A detailed review of the persistence, bioaccumulation, and toxicity of tributyltin compounds in aquatic environments was conducted by Environment Canada[2] for non-pesticidal uses of these compounds. A Notice summarizing the scientific considerations of a final follow-up ecological assessment report[3] was published by Environment Canada in the *Canada Gazette*, Part 1, for Organotin Substances) on August 8, 2009 under Section 68 of the *Canadian Environmental Protection Act* (CEPA) 1999. The report concluded that tributyltin compounds meet the TSMP Track 1 criteria for being:

- **Predominately anthropogenic**. Tributyltin compounds are present in the Canadian environment exclusively as a result of human activity. As such, tributyltin compounds are considered to have met the criteria of being predominately anthropogenic.
- **Persistent and Bioaccumulative**. Tributyltin compounds were observed to have half-life values in sediments up to 15 years exceeding the TSMP criterion for persistence in sediments (half-life $\geq$ 365 days in sediments). Tributyltin compounds have bioaccumulation factors (BAFs) ranging from 10 000 for marine periwinkles and oysters to 900 000 for freshwater mussels exceeding the TSMP criterion for bioaccumulation (BAF $\geq$ 5000). Tributyltin compounds meet criteria for persistence and bioaccumulation as defined by the *Persistent and Bioaccumulation Regulations* made under CEPA 1999.
- ***CEPA* –toxic**. Tributyltin compounds are harmful to aquatic organisms at low concentrations. They are entering, or may, enter the environment in a quantity or concentration or under condition that have or may have an immediate or long-term effect on the environment or its biological diversity. Therefore, tributyltin compounds meet the criterion under section 64 of CEPA 1999.

The proposed risk mitigation measures for non-pesticidal uses include addition of tributyltin compounds to the Virtual Elimination List (a prohibition regulation to be proposed under Section 93 of CEPA 1999).

For tributyltin uses regulated under the *PCPA*, the PMRA concluded that available information indicates that tributyltin compounds meet Track 1 criteria for persistence and bioaccumulation under the *Toxic Substances Management Plan* (TSMP). The PMRA also concluded that tributyltin compounds are toxic both on an acute and chronic basis to many aquatic organisms, including fish. These compounds are also highly toxic to molluscs, with chronic toxicity in oysters and clams occurring at fractional micrograms per litre concentrations.

Consequently, under the authority of the *PCPA* and its Regulations, PMRA is proposing the phase-out of all remaining registrations for the sale and use of products containing these tributyltin compounds. This proposal affects all end-use products containing tributyltin oxide (BTO) and tri-n-butyltin maleate (TBM) registered in Canada.

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2 Review of the Persistence, Bioaccumulation and Toxicity of Tributyltin in Aquatic Environments in Relation to Canada's Toxic Substances Management Policy, R. James Maguire, Water Qual. Res. J. Canada, Volume 35, No. 4, 633-679.

3 Follow-up to the 1993 Ecological Risk Assessment of Organotin Substances on Canada's Domestic Substances List, Environment Canada 2009.

Next Steps

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

The PMRA is seeking quantitative and/or qualitative information on the economic and social importance of tributyltins to specific industries and information on the availability and viability of alternative chemical and non-chemical pest management practices for the site and pest combinations registered for tributyltins. This information will allow the PMRA to refine sustainable pest management options for tributyltins.

Before making a final re-evaluation decision on tributyltin oxide and tri-n-butyltin maleate, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and the Special Review Decision Document SRD2002-01 can be found on our website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP and other Environment Canada reports are available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for tributyltin compounds is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

Appendix I Registered Products Containing Tributyltin as of 11 December 2009

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (% w/w)
Tributyltin oxide [BTO]					
18077	Technical	Arkema Inc.	Biomet TBTO	Solution	93.3%
12880	Commercial	Sanitized Inc.	Sanitized Brand Bacteriostat RB-475 Liquid	Solution	5%
12895	Commercial	Thomson Research Associates	Ultrafresh 300 DD Nonionic Liquid Germistat	Emulsifiable concentrate	1.06%
13538	Commercial	Sanitized Inc.	Sanitized Brand Bacteriostat OA-P Liquid	Solution	10%
5565	Domestic	Osmose-Pentox Inc.	Pentox Wood Preservative Green	Solution	0.075%
18972	Domestic	Osmose-Pentox Inc.	Osmose End Cut Wood Preservative (Moss)	Solution	0.075%
23984	Domestic	Cuprinol Group	Cuprinol Siding Stain & Preservative (Various Colours)	Solution	0.3%
Tri-n-butyltin maleate [TBM]					
14498	Commercial	Thomson Research Associates	Ultrafresh DM-50N	Emulsifiable concentrate	25%